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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,819	08/12/2002	Ronald Vale	UCSD-06783	1389

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EXAMINER	
SHIBUYA, MARK LANCE	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,819	VALE ET AL.	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-69 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-33, 35, 36, 41-69, drawn to methods of testing compounds for their ability to modulate cytoskeletal function comprising detecting changes in binding of a first cytoskeletal component to a second cytoskeletal component, wherein said detecting does not involve detecting the active movement of the cytoskeletal components.

Group II, claim(s) 34, drawn to the method of claim 19 of testing compounds for their ability to modulate cytoskeletal function comprising detecting changes in binding of at least two different first cytoskeletal component to at least two different second cytoskeletal component.

Group III, claim(s) 37-40, drawn to methods of testing compounds for their ability to modulate cytoskeletal function comprising detecting changes in coupling between ATP hydrolysis and force generation.

Further Restriction For Lack of Unity of Invention

A) In addition each of Groups I, II and III (methods of testing compounds) detailed above reads on patentably distinct Groups. Each of the Groups I, II and III are further divided into multiple groups each representing a different pairwise combination of cytoskeletal component (see, for example, **Table 1**, pp. 23-25 of the instant specification). Group II is drawn to methods comprising at least two of a first cytoskeletal component

and at least two of a second cytoskeletal component. Firstly, the claimed methods lack a special technical feature, (see below in reference to the prior art of Woo, WO 94/08041). Secondly, the multiple methods of each Group comprise pairwise combinations of cytoskeletal component that have no unifying structural relationship that is substantially responsible for a common property or activity. Indeed, the term cytoskeletal components encompasses many different properties and activities. The instant disclosure states: "The number and identity of cytoskeleton components that have been identified thus far are legion, and far too numerous to be completely listed here." The instant disclosure at p. 22, lines 19-20. Thus a further restriction is applied to each of Groups I, II and III.

If one of Groups I or III is elected, the elected **further restricted Group** *must* result in a method comprising a single pair of a specific first cytoskeletal component and a specific second cytoskeletal component. If Group II is elected, the elected **further restricted Group** *must* result in a method comprising specific, named pairwise cytoskeletal components.

For this response to be complete, applicants should provide elected first and second cytoskeletal components, as appropriate, and list all of the claims readable upon the elected pairwise combination.

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each product is assumed to be a patentably distinct invention, absent evidence to the contrary.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking the claims is anticipated by the reference of WO 94/08041, Inventor Woo. Thus there is no special technical feature linking the claims.

In particular, Woo, throughout the publication and abstract, and for example, at p. 3, line 31-p. 5, line 14, teach a method of screening for agents, reading on testing multiple compositions, for their ability to ability to form cysts in vitro, which relates to proper functioning of the cytoskeleton. Woo states:

> One of the surprising discoveries of the present invention is that agents which affect the proper functioning of the cytoskeleton or which affect the transport of membrane proteins to the cell membrane can be used to treat cysts and cystic diseases. Such agents include compounds which depolymerize microtubules, such as colchicine, vinblastine, vincristine, and nocodazole, as well as compounds which stabilize microtubule structures, such as taxol and derivatives thereof. Also included in the list of compounds which can be used to treat cysts and cystic disease are compounds which depolymerize actin microfilaments, such as cytochalasin B and cytochalasin D, those which stabilize actin microfilaments, such as phalloidin, and some, such as griseofulvin, *which interfere with microtubule function by an unknown mechanism.* [Emphasis added].

Woo, at p. 4, lines 3-5. Also, Woo contemplates using the cyst assay to identify compounds that modulate cytoskeletal function. Woo claims:

> 24. A method of screening an agent in vitro in order to determine its effectiveness in treating a cystic disorder, comprising: forming a suspension of cells which form cysts in vivo in a medium comprising an agent to be tested for its ability to inhibit cyst formation; culturing said cells in said medium on a solid phase without formation of a layer of said cells on the surface of said solid phase; detecting the extent to which said cells form cysts; comparing the detected extent of cyst formation with the extent of cyst formation expected if said cells were cultured in a medium without said agent; and identifying said agent as effective in treating a cystic

disorder if the detected extent of cyst formation is less than the expected extent of cyst formation in medium without said agent.

25. The method of Claim 24, wherein said agent is a compound that interferes with the normal metabolism of a cytoskeletal component.

Woo, in claims 24 and 25 of the WO 94/08041 application.

Woo discloses cells that are "cultured on a solid phase", wherein the solid phase is agarose (Woo at p. 7, lines 4-7), which reads on adhering a first cytoskeletal component to a solid support (as in instant claim 1), wherein the living cells naturally comprise cytoskeletal elements, including microtubules and actin microfilaments, whose monomers are first and second cytoskeletal components (see, e.g., Woo at p. 18, lines 10-19). Woo teaches contacting the cells on the solid phase agarose with multiple test compositions (see, e.g., Table II, p. 15 and Example 5 of the WO 94/08041 publication), as in claim 1. Woo teaches detecting changes in the binding affinity of the second cytoskeletal component to the first cytoskeletal component, by observing inhibition of cyst formation, which is method of detecting that does not involve detecting the active movement of cytoskeletal components, as in claim 1. In Example 5, Woo teaches discovering that brefeldin A is an inhibitor of cyst formation, (see, e.g., Table II, p. 15 and Example 5 of the WO 94/08041 publication), and states that "[a]lthough the mode of action of brefeldin A has not yet been characterized, it has been observed that this drug blocks the movement of membrane proteins between the endoplasmic reticulum and the Golgi bodies." WO 94/08041 publication at p. 19, lines 12-14. Woo then reasons that the action of brefeldin A in inhibiting cyst formation, demonstrates the ability to modulate cytoskeletal function (as in the instant claims), stating that "[o]ne reason for this blockage of movement could be due to some interference with the microtubules

along which such vesicles [containing the membrane proteins] are transported." WO 94/08041 publication at p. 19, lines 17-18. Thus Woo teaches screening compounds for modulation of cytoskeletal function by assaying for inhibition of cyst formation.

Election of Species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

4. Applicant must elect a particular and specific species of test composition, such homo-phenylalanine (see p. 30-35 of the instant disclosure).

5. Applicant must elect a particular and specific species of assay system, such as an assay systems that employs a reporter molecule that is a fluorophore, wherein the fluorophore is GFP, and is detected by total internal reflection microscopy; or where the assay system is an ATPase assay, or wherein the assay system is a two hybrid system. This election must be consonant with the election of the Group, and the election of the pairwise cytoskeletal composition.

6. Applicant must elect a species of lead compound, such as identified for animal or human disease, bioagriculture, herbicide, pesticide or fungicide, or diagnostic.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species of assay system: claims 7-10, 28-31 and 44-53.

Species of test composition: claims 35, 57-64, and 67-69

The following claim(s) are generic: 1, 18, 19, 26, 33, 37, and 41.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Firstly, the claimed methods lack a special technical feature, (see below in reference to the prior art of Woo, WO 94/08041). Secondly, the assay systems and test compositions, absent evidence to the contrary, are not patentably distinct and are not obvious over each other.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Shibuya
Examiner
Art Unit 1639

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